



Food and Drug Administration  
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September 16, 2015

Eurogreen International Inc  
David Hsieh  
General Manager  
No.48, Ln.220, Sec.1, Fuzun Rd., Yuanlin Township  
Changhua County, 51055  
Taiwan

Re: K143557  
Trade/Device Name: "SupaScoota" Motorized Vehicle  
Regulation Number: 21 CFR 890.3800  
Regulation Name: Motorized Three-Wheeled Vehicle  
Regulatory Class: Class II  
Product Code: INI  
Dated: August 10, 2015  
Received: August 12, 2015

Dear Mr. Hsieh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Michael J. Hoffmann -S**

for Carlos L. Peña, PhD, MS  
Director  
Division of Neurological  
and Physical Medicine Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K143557

Device Name

"SupaScoota" Motorized Vehicle

Indications for Use (Describe)

As a motorized portable electric vehicle for indoor or outside use by persons with medical conditions requiring assistance.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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	510(k) Summary	

Date of preparation : Aug. 07, 2015

### 5.1 Applicant Information

Type of Submission	Original Application- Traditional 510(k)
Applicant Name	EUROGREEN INTERNATIONAL INC.
Address	No.48, Ln. 220, Sec. 1, Fuzun Rd., Yuanlin Township, Changhua County, Taiwan
Phone	+886-4-8319633
Fax	+886-4-8332226
Contact Person	David Hsieh
Contact Title	President
Contact E-mail	<a href="mailto:sales@lawia.com">sales@lawia.com</a>

### 5.2 Device Description

Intended Use : As a motorized portable electric vehicle for indoor or outside use by persons with medical conditions requiring assistance.

Item	Description
Common Name	Motorized vehicle
Trade Name	"SupaScoota" Motorized vehicle
Classification Name	Motorized vehicle
Regulation Number	890.3800
Product Code	INI
Device Class	Class 2
Model	STD01/ STD02/ HD01/ HD02/ SPC01/ SPC02/ SP01/ SP02/ MD01/ MD02

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Number of wheels	3 wheels+ 2 stabilizer wheels 4 wheels
Front wheel size	200 x 65 mm ( 8 x 2.5") 200 x 50mm (8 x 2")
Rear wheel size	200 x 65 mm ( 8 x 2.5") 260 x 85mm (10 x 3")
Ground clearance	<u>60~65 mm (2.4~2.6")</u>
Length	945~1100 mm (37~43")
Width	550~600 mm (22~26")
Height	<u>820mm (32")-930mm (36.6")</u>
Seat height	<u>560mm (22")- 620mm (24.5")</u>
Max Loading <u>(weight capacity)</u>	80 ~125kg (175~275 lbs)
Weight without seat/ battery	14.9~21.9 kg (33~48.5 lbs)
Weight of Seat	5.8~11.5 kg (13~25 lbs) (include seat frame & arm rest)
<u>Weight w/battery</u>	<u>27.3~42.6 kg (60~94 lbs)</u>
Brakes	Dynamic braking and electromagnetic brake
Turn Radius	780~975 mm
Motor Output	1 x 180W/ 2 x 150 W/ 2 x 180 W
Battery	SLA: 12V-20ah/ 24V-15ah Lithium: 12V-20ah/ / 24V-15ah
<u>On/off board battery chargers</u>	<u>Off board battery charger</u>
Max Speed	6.5 kph (4 mph)/ 9.0 kph (5.6 mph)
Travel Distance	SLA: 13~18km (8~11 miles)

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	Lithium: 16~22 km (10~13.6 miles)
<u>Climbing angle</u>	<u>8~12 Degrees</u>
<u>Steering wheels/drive wheels</u>	<u>200mm (8") / 200mm (8")</u> <u>200mm (8") / 260mm (10")</u>

	Standard		Heavy Duty		Superior Duty		Sport		MD	
	STD01	STD02	HD01	HD02	SPC01	SPC02	SP01	SP02	MD01	MD02
Number of wheels	3 wheels+2 stabilizer wheels	4 wheels	3 wheels+2 stabilizer wheels	4 wheels	4 wheels	4 wheels	4 wheels	4 wheels	3 wheels+2 stabilizer wheels	4 wheels
Front wheel size	200 x 65 mm (8x2.5")	200 x 50 mm (8x2")	200 x 65 mm (8x2.5")	200 x 50 mm (8x2")	200 x 50 mm (8x2")		200 x 65 mm (8x2.5")		200 x 65 mm (8x2.5")	200 x 50 mm (8x2")
Rear wheel size	200 x 65 mm (8x2.5")	200 x 65 mm (8x2.5")	200 x 65 mm (8x2.5")	200 x 65 mm (8x2.5")	200 x 65 mm (8x2.5")	260 x 85mm (10 x 3")	260 x 85mm (10 x 3")		200 x 65 mm (8x2.5")	200 x 65 mm (8x2.5")
Ground clearance	60 mm (2.4")	60 mm (2.4")	60 mm (2.4")	60 mm (2.4")	60 mm (2.4")	65 mm (2.6")	65 mm (2.6")	65 mm (2.6")	60 mm (2.4")	60 mm (2.4")
Length	945 mm (37")	1000 mm (39")	970 mm (38" )	1010 mm (40" )	1000 mm (39")	1040 mm (41")	1100 mm (43" )		945mm (37" )	1000mm (39" )
Width	550 mm (22")	550 mm (22")	570 mm (22.5" )	570 mm (22.5" )	570 mm (22.5" )	600 mm (24" )	600 mm (24" )		570mm (22.5" )	
Max Loading	80 kgs (175 lbs)	80 kgs (175 lbs)	125 kgs (275 lbs)	125 kgs (275 lbs)	105 kgs (230 lbs)		125 kgs (275 lbs)		125kg (275 lbs)	
Weight without seat	15.6 kgs (34.5 lbs)	14.9 kgs (33 lbs)	20.3 (44.5 lbs)	19.8 kgs (43.5 lbs)	17.8 kgs (39 lbs)	19.5 kgs (44 lbs)	21.9 kgs (48.5 lbs)		17.7kg (39 lbs)	18.6kg (41 lbs)
Weight of Seat	5.8 kgs (13 lbs)	5.8 kgs (13 lbs)	7.7 kg (17 lbs)	7.7 kg (17 lbs)	5.8 kgs (13 lbs) (include seat frame &		8.6 kgs (19 lbs)	11.5 kgs (25 lbs)	5.8kg (13 lbs included seat frame)	

	(include seat frame & arm rest)	(include seat frame & arm rest)	(include seat frame & arm rest)	(include seat frame & arm rest)	arm rest)	(include seat frame & arm rest)	(include seat frame & arm rest)	
Turn Radius	780 mm (31" )	900 mm (35.5" )	780 mm (31" )	910 mm (36" )	875 mm (34.5" )	895 mm (35" )	975 mm (38.5" )	780mm (31" ) 875mm (34.5" )
Brakes	Dynamic braking and electromagnetic brake		Dynamic braking and electromagnetic brake		Dynamic braking and electromagnetic brake		Dynamic braking and electromagnetic brake	
Motor Output	DC 12V x 180W		2 x 150W		2 x 150 W		2 x 180 W	
Battery	SLA: 12V-20ah		SLA:24V-15ah		SLA: 24V-15ah		SLA: 24V-15ah	
	Lithium: 12V-20ah		Lithium: 24V-15ah		Lithium: 24V-15ah		Lithium: 24V-15ah	
Max Speed	6.5 kph (4 mph)		6.5 kph (4 mph)		6.5 kph (4 mph)		9.0 kph (5.6 kph)	
Climbing angle	9 Degrees		9~12 Degrees		9 Degrees		9 Degrees	
Travel Distance	SLA: 13 km (8 miles)		SLA: 16 km (10 miles)		SLA:18 km (11 miles)		SLA:14 km (8.5 miles)	
	Lithium: 16 km (10 miles)		Lithium: 20 km (12.4 miles)		Lithium: 22 km (13.6 miles)		Lithium: 18 km (11 miles)	



### 5.3 Equivalence comparison to marketed device

Technological characteristics :

The device features and use parameters of the Freerider and HEARTWAY scooters are very similar Both are battery operated and have brake systems. Batteries capacity and battery chargers are similar and are provided with the scooters. Use parameters are very similar, varying only in minor parameters such as the grade climbable by the respective scooters.

	EUROGREEN International Inc.	HEARTWAY USA.	FREERIDER Corp.
K number	-	K101143 Appendix 9.1	K110165 Appendix 9.2
Indication for Use	As a motorized portable electric vehicle for indoor or outside use by persons with medical conditions requiring assistance.	The device is intended for medical purposes to provide mobility to persons restricted to a seated position.	The device provides transportation for an elderly or disabled person. It can be used in variety of indoor and outdoor settings.
Model Type	STD01/ STD02/ SPC01/ SPC02/ HD01/ HD02/ SP01/ SP02/ MD01/ MD02	S11	FR168-3A3
Front wheel size	200 x 65 mm ( 8 x 2.5") 200 x 50mm (8 x 2")	240 x 75 mm (9.5 x 3" )	200 x 50 mm
Rear wheel size	200 x 65 mm ( 8 x 2.5") 260 x 85mm (10 x 3")	Option	200 x 50 mm
Ground clearance	50 mm (2")	70 mm	86 mm

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Length	945~1100 mm (37~43")	1070 mm (42" )	945 mm
Width	550~600 mm (22~26")	580 mm (23" )	508 mm
Height	<u>820mm (32")-930mm (36.6")</u>	<u>915mm</u>	-
Seat height	<u>560mm (22")- 620mm (24.5")</u>	<u>400mm</u>	-
Max Loading (weight capacity)	80 ~125kg (175~275 lbs)	120 kg (265 lbs)	<u>110 kg(250 lbs)</u>
Weight without seat/ battery	14.9~21.9 kg (33~48.5 lbs)	<u>48kgs(105lbs)</u>	-
Weight of Seat (include seat frame & arm rest)	5.8~11.5 kg (13~25 lbs)	-	-
Weight w/battery	<u>27.3~42.6 kg</u> <u>(60~94 lbs)</u>	<u>58kgs(127.6 lbs)</u>	-
Brakes	Dynamic braking and electromagnetic brake	-	-
Turn Radius	780~975 mm	1980mm	<u>820 mm</u>
Motor Output	1 x 180W/ 2 x 150 W/ 2 x 180 W	400 Watt	-
Battery	SLA: 12V-20ah/ 24V-15ah Lithium: 12V-20ah/ / 24V-15ah	12V-22ah x 2 pcs	<u>24V</u> 12ah
on/off board battery chargers	<u>Off board battery charger</u>	<u>Off board battery</u> <u>charger</u>	<u>Off board battery</u> <u>charger</u>
Max Speed (forward)	6.5 kph (4 mph) 9.0 kph (5.6 kph)	8 kph (5 mph)	<u>6.5 kph (4 mph)</u>
Travel Distance	SLA: 13~18 km (8~11 miles) Lithium: 16~22 km (10~13.6 miles)	<u>20km (13 miles)</u>	<u>16km (10 miles)</u>

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Climbing angle	8~12 Degrees	10° Degrees	-
Steering wheels/drive wheels	200mm (8") / 200mm (8") 200mm (8") / 260mm (10")	- / 240mmx75mm(9.5"x3")	-

## 5.4 Safety and Effectiveness

The substantially equivalence to other commercially products (motorized vehicle) including FREERIDER MODEL LUGGIE MODEL (K110165) and HEART WAY Power Mobility Scooter, S11 (K101143). The comparison table in below table list the primary technical aspects and specifications that are pertinent to motorized three-wheeled vehicle. The "SupaScoota" Motorized is as safe and effective as the predicate devices.

## 5.5 Non-clinical Testing

"SupaScoota" Motorized vehicle has done the series test to confirmation its safety and effectiveness in pre-clinical test. The tests are conducted with ISO 7176-1 serial standards. All test results are in compliance with it and were similar to predicate device.

- ISO 7176-1 : Static stability test
- ISO 7176-2 : Dynamic stability test
- ISO 7176-3 : Efficiency of brakes tests
- ISO 7176-4 : Theoretical distance range tests
- ISO 7176-5 : Overall dimensions, Mass, Turning, Diameter tests

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- ISO 7176-6 : Maximum speed, acceleration and retardation tests
- ISO 7176-7 : Seating and wheel dimension tests
- ISO 7176-8 : Static, impact and fatigue strengths tests
- ISO 7176-9 : Climatic tests
- ISO 7176-10 : Obstacle-climbing ability tests
- ISO 7176-11 : Test dummies
- ISO 7176-13 : Determination of coefficient of friction of test surfaces
- ISO 7176-14 : Power and control system
- ISO 7176-15 : Wheelchairs -- Part 15: Requirements for information disclosure, documentation and labelling.
- ISO 7176-21 (EN 12184) : EMC test

## 5.6 Conclusion

“SupaScoota” Motorized vehicle is a safe, reliable and effective medical device, meeting all declared requirements of its intended use and the device does not introduce new risks and does not present any adverse health effects or safety risks to patients when used as intended.